

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's file reference BASF/NAE 1024/99PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP00/07625	International filing date (day/month/year) 05 August 2000 (05.08.00)	Priority date (day/month/year) 15 September 1999 (15.09.99)
International Patent Classification (IPC) or national classification and IPC C12N 15/82		
Applicant BASF PLANT SCIENCE GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 14 March 2001 (14.03.01)	Date of completion of this report 11 December 2001 (11.12.2001)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

Form PCT/IPEA/409 (cover sheet) (July 1998)

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I. Basis of the report.

1. With regard to the elements of the international application:*

☐ the international application as originally filed☒ the description:

pages _____ 1-18 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

☒ the claims:

pages _____ 1-17 _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

☒ the drawings:

pages _____ 1/4-4/4 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
 pages _____, filed with the demand.
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☒ furnished subsequently to this Authority in written form.
☒ furnished subsequently to this Authority in computer readable form.
☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

Continuation of: Box I.6.

The sequence protocol submitted with the letter of 10 October 2000 (2 pages, 2 sequences) is not part of the application (PCT Rule 13ter.1(f)).

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-17	NO
Inventive step (IS)	Claims		YES
	Claims	1-17	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims		NO

2. Citations and explanations

Documents

For the purposes of this international preliminary examination report (IPER), the documents listed in the international search report (ISR) of 28 November 2000 are abbreviated to D1-D5 according to the sequence in which they appear in the ISR.

1 **Abstract of the application**

The present application describes the transfer of a DNA construct comprising the 35S promoter, the AATP1 sequence (*Arabidopsis thaliana* ATP/ADP translocator gene) in sense orientation, and a polyadenylation point (plasmid pBIN AR-AATP1) in a potato plant (*Solanum tuberosum*) with the help of *Agrobacterium tumefaciens* (Examples 4 and 5). The content of certain amino acids in said plant is thus increased in comparison with wild varieties of the plant (see Table 1).

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2 **Novelty and inventive step (PCT Article 33(2) and (3))**

- 2.1 The subject matter of Claims 1-17 does not meet the requirements of PCT Article 33(2) and (3).
- 2.2 The plants described in D1 (Tjaden et al.) were transformed in the same way as the plants of the present application. A DNA construct comprising the 35S promoter, the AATP1 sequence (plastidic ATP/ADP translocator gene) in sense (plasmid pBIN AR-AATP1) or antisense orientation, and a polyadenylation point is transformed in a potato plant (*Solanum tuberosum*) with the help of *Agrobacterium tumefaciens* (see D1, page 538, right-hand column together with Examples 4-7 of this application; see also page 6, lines 20-22 of the present description). The overexpression of the plastidic ATP/ADP translocator gene is achieved by transforming the plants with the sense sequence (see D1, page 532, right-hand column).
- 2.3 The IPEA is also of the opinion that the words "altered such that" define such a large scope of protection that any known plant with altered regulative sequences and/or an altered gene copy number of a plastidic AATP gene prejudices the novelty of independent Claim 1. The "alteration" is not sufficiently defined as to lend novelty to the subject matter of independent Claim 1 over the prior art.
- 2.4 D2 (WO-A-94/10320) discloses the "antisense expression" of an ATP/ADP translocator gene in potato plants (see, for example, page 4, lines 28-32

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of D2). This corresponds to Examples 6 and 7 of the present application. In contrast to the present application, D2 uses a mitochondrial ATP/ADP transporter. The feature of the "plastidic" ATP/ADP transporter is not, however, included in independent Claim 1. D2 therefore prejudices the novelty of the subject matter of Claims 1, 3, 5, 13, 14, 16 and 17.

2.5 D1 and D2 do not specify the content of essential amino acids. Since the methods of D1 and D2 and that of the present application do not differ (result: increased or reduced quantity of an ATP/ADP translocator protein), the result of the methods (increased or reduced quantity of certain amino acids) is an inherent feature of the transformed plants of D1 and D2. The subject matter of Claims 1-5 and 13-17 therefore cannot be distinguished from the transformed plants and methods of D1 and D2 (PCT Article 33(2) and (3)).

2.6 Independent Claim 6 relates to a gene sequence per se. The DNA sequence, obtainable under the EMBL Accession Number Z49227, was already described in D3 (Kampfenkel 374: 351-355) and D4 (Z49227).

D4 contains no technical teaching on how to proceed technically. It is, however, pointed out that indications concerning an intended type of use (Claim 6: "...for use in a plant...") in a claim directed to an object cannot be regarded as distinguishing features, i.e. the claim relates to the product per se (PCT Guidelines, Chapter IV-7.6). The subject matter of Claims 6-12 is therefore not allowable under PCT Article 33(2) and (3).

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2.7 A "method for increasing the content of essential amino acids in a plant" characterised by the features of Claim 15 would have been considered novel by this authority.

3 Industrial applicability (PCT Article 33(4))

Claims 1-17 meet the requirements of PCT Article 33(4).

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO-A-9958654	18 November 1999 (18.11.1999)	12 May 1999 (12.05.1999)	13 May 1998 (13.05.1998)

See annexe

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosureDate of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box VI

The above document was published between the priority date and the filing date of the present application and is therefore not considered to be prior art under PCT Rule 64.1(b). WO-A-99/58654 (D5), however, claims an earlier priority date than the present application and will therefore be relevant to the assessment of the novelty of the claimed subject matter in the regional phase. D5 discloses transformed plants and derivatives thereof, the genetic modification consisting in the introduction of an ADP/ATP translocator gene (AATP) from *Arabidopsis thaliana*.

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